

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS**

No. 03-2619V

Filed: October 17, 2013

Not for Publication

KERRI SPEIGHTS, parent of
TYLER SPEIGHTS, a minor,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Autism; Chronic Mucocutaneous
Candidiasis; CMC; Statute of
Limitations; Significant Aggravation;
Equitable Tolling; Vaccine Act
Entitlement; Denial Without Hearing

Brian R. Arnold, Esq., Brian R. Arnold & Associates, Dallas, TX, for petitioner.
Ann Martin, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Chief Special Master:

On November 3, 2003, Kerri Speights ["petitioner"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² [the "Vaccine Act" or "Program"], on behalf of her minor son, Tyler Speights ["Tyler"]. Petitioner initially alleged that Tyler's autism spectrum disorder ["ASD"] was caused by one or more of the vaccines he received.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

Subsequently, petitioner alleged that Tyler's vaccinations caused or significantly aggravated his immunodeficiency disorder (chronic mucocutaneous candidiasis ["CMC"]) and/or his developmental regression.³

Because I conclude that the petition was untimely filed, even under a significant aggravation theory, and further that the circumstances in this case do not warrant equitable tolling, this case is dismissed.

I. Procedural History.

A. The Short-Form Petition.

By filing a "short-form" petition for vaccine compensation, petitioner opted into the Omnibus Autism Proceeding ["OAP"].⁴

The OAP was created to resolve what ultimately totaled about 5,700 petitions alleging that vaccines or the thimerosal preservative contained in some vaccines caused ASDs. In an omnibus proceeding, test cases are selected for hearings in which the parties present evidence generally applicable to the cases in the omnibus proceeding, as well as evidence specific to the test cases. The results in the test cases do not bind the parties in the remaining omnibus cases, but the body of evidence thus created can be used to resolve the remaining cases.⁵ In the OAP, three test cases were selected for each of the two theories of vaccine causation advanced by the petitioners' bar. Hearings in the test cases were conducted in 2007 and 2008, and decisions were issued in 2009 and 2010.⁶

³ Petitioner's original and amended claims, as well as Tyler's medical history, are discussed in further detail below.

⁴ By electing to file a Short-Form Autism Petition for Vaccine Compensation, petitioners alleged that:

[a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza[e] Type B (HIB) vaccinations; or by some combination of the two.

Autism General Order #1, Exhibit A, Master Autism Petition for Vaccine Compensation, 2002 WL 31696785, at *8 (Fed. Cl. Spec. Mstr. July 3, 2002), *available at* <http://www.uscfc.uscourts.gov/node/2718>.

⁵ A more detailed explanation of the creation of the OAP and the effects of opting into it can be found in *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁶ The Theory 1 cases are *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Petitioners in *Snyder* did not appeal the

To position Tyler's case for resolution upon the conclusion of the test cases, I ordered petitioner to file all medical records from Tyler's birth through the later of petitioner's filing date or the date of Tyler's ASD diagnosis. Order, issued Nov. 14, 2008. Petitioner filed medical records on February 12, 2009. Petitioner's Exhibits ["Pet. Exs."] 1-32.⁷

On March 2, 2009, respondent moved to dismiss petitioner's case as untimely ["Res. Mot. to Dismiss"], asserting that the petition was filed outside the Vaccine Act's three-year statute of limitations. Res. Mot. to Dismiss at 1 (citing § 16(a)(2)). Respondent argued that Ms. Speights should have filed her petition by no later than July 13, 200[1],⁸ because the first symptom or manifestation of onset of Tyler's ASD occurred, when he was approximately 20 months old (around July 13, 1998), more than three years prior to petitioner's November 3, 2003 filing date. Res. Mot. to Dismiss at 3-4.

Petitioner responded to the motion to dismiss on April 8, 2009 ["Pet. Resp. to Mot. to Dismiss"], contending that her petition was timely filed. Ms. Speights argued that the Vaccine Act's statutory limitations period began on August 8, 2001, the date of Tyler's ASD diagnosis, and that she therefore had until August 8, 2004 to file a petition. Pet. Resp. to Mot. to Dismiss at 2-4. A ruling on the motion to dismiss was deferred, pending the appellate review of the test case decisions.

On September 15, 2010, I ordered Ms. Speights to inform the court whether, in light of the results in the OAP test cases, she wanted to proceed with her claim or move to dismiss it. On November 17, 2010, after petitioner failed to comply with my order, I ordered petitioner to show cause why her case should not be dismissed for failure to prosecute. On December 21, 2010, Mr. Brian Arnold became Ms. Speights's counsel.

B. First Amended Petition.

On January 7, 2011, I ordered petitioner to file an amended petition, setting forth the vaccines responsible for Tyler's condition and a theory of causation. On February 11, 2011, petitioner filed an amended petition ["First Am. Pet."], alleging that Tyler "suffered an acute complication or sequella of an illness, disability, injury, or condition"

decision of the U.S. Court of Federal Claims. The Theory 2 cases are *Dwyer*, 2010 WL 892250; *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). The petitioners in each of the three Theory 2 cases chose not to appeal.

⁷ Petitioner failed to submit Exhibit 6, which was described in the Table of Contents as "Record of Information Sheets from Dr. Cramer."

⁸ Respondent mistakenly stated that "this case should have been filed no later than July 13, 2000." Res. Mot. to Dismiss at 4. Based on Tyler's date of birth, November 13, 1996 (Pet. Ex. 1), and respondent's reference to the medical records indicating his regression began around 20 months, about July 13, 1998 (Res. Mot. to Dismiss at 3), it is evident that respondent miscalculated three years from July 13, 1998.

as a direct result of the vaccines he received between birth and 33 months of age.⁹ First Am. Pet. at 2-3. Petitioner added that Tyler “suffered injury, or in the alternative suffered an aggravation of a medical condition as a result of his multiple vaccines.” *Id.* at 3. Although noting Tyler’s CMC¹⁰ diagnosis, petitioner ambiguously referred to “a multitude of reactions and problems” and “multiple physical and health problems following . . . vaccinations.” First Am. Pet. at 2-3.

On February 15, 2011, I ordered petitioner to file all outstanding medical records and an affidavit describing Tyler’s vaccinations and injuries. In petitioner’s affidavit [“Pet. Aff.”], filed on April 4, 2011, Ms. Speights stated her belief that Tyler no longer has an ASD diagnosis. She added that Tyler “continues to suffer from his injuries caused by the vaccine(s) which aggravated his condition.”¹¹ Subsequently, petitioner filed additional medical records.

On May 26, 2011, I stayed resolution of respondent’s motion to dismiss, noting that the statute of limitations issues in this case appeared similar to those raised in a case then pending before the Federal Circuit, *Cloer v. Sec’y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011) (en banc), *cert. denied*, 132 S. Ct. 1908 (2012). Following the decision in *Cloer*, I ordered the parties to file simultaneous briefs addressing the impact of *Cloer* on this case. Order, issued Aug. 19, 2011.

C. The Parties’ *Cloer* Briefs.

On September 19, 2011, respondent filed her brief addressing *Cloer* [“Res. Br.”]. In her brief, respondent noted the Federal Circuit’s holding that “[t]he statute of limitations in the Vaccine Act begins to run on the date of the occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought, and the symptom or manifestation of onset must be recognized as such by the medical profession at large.” Res. Br. at 3 (quoting *Cloer*, 654 F.3d at 1335).

Petitioner submitted her brief addressing *Cloer* [“Pet. Br.”] on October 18, 2011.¹² In her brief, petitioner asserted that her petition was timely filed (Pet. Br. at 7), or,

⁹ These vaccines included: “Hepatitis B1, DTP-HIB1, OPV 1PV1 [sic], Hepatitis B2, DTP-HIB2, OPV 1PV2 [sic], DTP-HIB3, Hepatitis B3, Varicella, Varivax, MMR, HIB4, DTAP4, and OPV3.” First Am. Pet. at 2.

¹⁰ Chronic mucocutaneous candidiasis is an immunodeficiency disorder in which the immune system does not adequately respond to *Candida* [“yeasts”] due to a primary defect in T-lymphocytes. NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) [“NELSON’S”] at 1056. It is characterized by chronic and severe yeast infections of the skin and mucus membranes. *Id.* Symptoms can present in the first few months of life. *Id.*

¹¹ Petitioner’s affidavit appeared incomplete. However, petitioner informed the court that the affidavit was complete as filed. See Order, issued April 7, 2011.

¹² Petitioner’s brief focused on Tyler’s CMC diagnosis, which is further discussed in Part II below. In this brief, petitioner set forth a theory and associated arguments not clearly presented in earlier filings.

alternatively, that equitable tolling is warranted (*Id.* at 4). Petitioner argued that Tyler's case is distinguishable from *Cloer* on the facts (*Id.* at 3 (citing *Cloer*, 654 F.3d 1322)), and that it should be evaluated under the standard set forth in *Setnes v. United States*, 57 Fed. Cl. 175 (2003) (Pet. Br. at 6).

According to petitioner, "Tyler's manifestation of onset occurred in November 2000 because it was the first time a medical professional had verified through reliable medical means that the vaccinations were the actual cause for Tyler's early childhood behavior." Pet. Br. at 6. Petitioner did not, however, specify which medical professional had so concluded. She noted that "Tyler's language delay was combined with other symptoms of normal child behavior which lead [sic] his pediatrician to assure petitioner that Tyler was reacting normally" and thus the earliest petitioner "knew or should have known" that vaccines caused Tyler's injury was November 3, 2000, when he was diagnosed with CMC.¹³ Pet. Br. at 7. Attempting to differentiate her case from *Cloer*, petitioner added that, unlike Tyler, Ms. Cloer received a diagnosis more than three years before filing her petition. *Id.* at 6 (citing *Cloer*, 654 F.3d at 1327-28).

Petitioner relied on *Setnes* as the basis for her contention that the standard for determining the timeliness of her petition should be subjective. Pet. Br. at 3 (citing *Setnes*, 57 Fed. Cl. at 179). According to petitioner, a subjective standard is appropriate because of the unique nature of CMC for which there is "no 'manifestation of onset' considered unless it is verified by a reliable medical and psychological [sic] means."¹⁴ Pet. Br. at 3 (citing *Setnes*, 57 Fed. Cl. at 179). Petitioner added that "when there is no clear start to an injury as in autism cases, there is no manifestation of onset until it is verified through a 'reliable medical and psychological means that a constellation of behaviors presented in a specific child meet [its] criteria.'" Pet. Br. at 5 (quoting *Setnes*, 57 Fed. Cl. at 175).

In addition to relying on *Setnes* to support her timeliness argument, petitioner also cited Judge Newman's dissent in *Brice v. Sec'y, HHS*, 240 F.3d 1367, 1374-78 (Fed. Cir. 2001), without explaining how this dissent supported her contention that "Tyler's case should be a good candidate for equitable tolling." Pet. Br. at 4. Petitioner also attempted to distinguish Tyler's case from that of the child in *Brice*. Acknowledging that unawareness of an obvious injury, like the seizure suffered by the vaccinee in *Brice*, is not grounds for equitable tolling, petitioner stated that "Tyler's condition was not diagnosed or accepted by his treating physicians until November of 2000." *Id.* (citing *Setnes*, 57 Fed. Cl. at 181; *Brice*, 240 F.3d at 1369).

On November 1, 2011, respondent filed a reply to petitioner's brief ["Res. Reply

¹³ Although petitioner asserted in her affidavit her belief that Tyler no longer has an ASD diagnosis, in her later-filed pleadings, she continued to reference developmental issues when discussing Tyler's CMC. See, e.g., Pet. Br. at 6; Petitioner's Second Amended Petition ["Second Am. Pet."] at 3.

¹⁴ The diagnosis of CMC would not involve either psychological testing or psychological specialists. Autism spectrum disorders may be diagnosed by psychologists, based on behavioral testing and observation.

Br.”], contending that petitioner’s arguments regarding the application of a discovery rule were meritless. Res. Reply Br. at 1-2. Respondent emphasized the Federal Circuit’s holding that “there is no explicit or implied discovery rule under the Vaccine Act.” *Id.* at 2 (citing *Cloer*, 654 F.3d at 1337). Respondent added that the statute of limitations is not triggered by a petitioner’s actual or presumed knowledge of either his adverse condition or the possible connection between a vaccine and his condition. Res. Reply Br. at 2 (citing *Cloer*, 654 F.3d at 1339). Finally, respondent noted that the Federal Circuit has thrice rejected the *Setnes* approach to triggering the running of the Vaccine Act’s statute of limitations. Res. Reply. Br. at 2-3 (citing *Markovich v. HHS*, 477 F.3d 1353, 1358 (Fed. Cir. 2007); *Wilkerson v. HHS*, 593 F.3d 1343, 1345 (Fed. Cir. 2010); *Cloer*, 654 F.3d at 1334-35).

During a December 6, 2012 status conference, I discussed the problems with petitioner’s supplemental *Cloer* brief. See Order, issued Dec. 7, 2012. I also addressed the deficiencies with petitioner’s amended petition, particularly petitioner’s failure to specify the alleged vaccine-caused injuries and the responsible vaccine(s). See *id.* Accordingly, I ordered petitioner to file a second amended petition, clearly identifying the alleged vaccine-caused injuries, the vaccines responsible, and the exact theory petitioner would attempt to prove with an expert report. *Id.*

D. Petitioner’s Motion to Dismiss.

On February 15, 2013, petitioner, instead of filing a second amended petition, filed a motion to dismiss [“Pet. Mot. to Dismiss”]. In her motion, petitioner noted her realization that retaining an expert and proving entitlement would be difficult. Pet. Mot. to Dismiss at 1. However, on February 18, 2013, petitioner moved to strike her motion to dismiss [“Pet. Mot. to Strike”], indicating that she had located potentially supportive evidence. Pet. Mot. to Strike at 1. I granted petitioner’s motion to strike and ordered her to file the additional evidence. Order, issued Feb. 19, 2013, at 2. I also ordered petitioner to file a second amended petition. *Id.*

E. Second Amended Petition.

On March 7, 2013, petitioner filed a second amended petition, which constitutes the operative petition for evaluating petitioner’s claims. Although the second amended petition is still ambiguous as to the alleged vaccine injury, it appears that petitioner links Tyler’s vaccinations to both his CMC and his developmental regression. Second Am. Pet. at 3 (“After further testing it was determined that the vaccines were aggravating his CMC condition and causing regression in the child’s development.”) (citing Pet. Ex. 8, p. 11).¹⁵ Petitioner asserts that Tyler’s vaccinations caused or significantly aggravated his

¹⁵ Petitioner claims that, “[o]n or about November 12, 2000, Tyler’s physicians traced back Tyler’s CMC and vaccine injuries . . . to his vaccines. . . . Petitioner filed her [p]etition for compensation on November 3, 2003, which is within three (3) years of Petitioner’s notice of vaccine related injuries.” Second Am. Pet. at 7 (emphasis added). Contrary to my February 19, 2013 order, petitioner again used ambiguous terms like “vaccine injuries” to describe Tyler’s condition.

condition. Second Am. Pet. at 5. She claims that her original petition, filed on November 3, 2003, was timely because Tyler's physician's traced his "CMC and vaccine injuries" to his vaccines on November 12, 2000. *Id.* at 7. Alternatively, she again asserts that her case warrants equitable tolling because she was "misinformed and . . . not given information as required by statute, which would have allowed [her] to file a claim . . . sooner." *Id.* Specifically, petitioner states that Tyler's treating physicians never notified her of the Vaccine Program. *Id.* at 5. Petitioner failed to file the evidence referenced in her motion to strike or other evidence supportive of her claims of misinformation. I therefore ordered her to show cause why her case should not be dismissed. Order, issued Apr. 12, 2013.

Petitioner filed additional evidence to support her equitable tolling claim on May 13, 2013. Pet. Ex. 39. According to petitioner's response to my show cause order ["Pet. Show Cause Resp."], the additional evidence, consisting of copies of vaccine information pamphlets that Ms. Speights claims she was given at the time of Tyler's vaccinations,¹⁶ did not put her on notice of the existence of the Vaccine Program. Pet. Show Cause Resp., filed May 13, 2013, at 3.

On June 21, 2013, I ordered respondent to address the allegations set forth in petitioner's second amended petition. In her response ["Res. Resp."], filed July 23, 2013, respondent reasserts her position that petitioner's case must be dismissed for untimely filing. Res. Resp. at 1. Respondent argues that Tyler experienced symptoms of CMC as early as October 5, 2000, more than three years before Ms. Speights filed her petition. *Id.* at 2 (citing Pet. Ex. 14, p. 3). Respondent adds that Tyler's medical records do not support petitioner's significant aggravation claim. Res. Resp. at 2. Commenting on the "unacceptabl[e]" vagueness of the second amended petition, respondent notes that "petitioner [did] not identify *any* specific vaccine-related manifestations of CMC occurring after November 3, 2003."¹⁷ *Id.* (citing Second Am. Pet. at 4-5). Finally, respondent asserts that ignorance of the law is "insufficient to warrant application of the extraordinary relief of equitable tolling." Res. Resp. at 4.

II. Relevant Medical History.

Tyler was born on November 13, 1996. Pet. Exs. 1; 2, p. 5. Tyler's Apgar scores were 7 and 9,¹⁸ and his size was "appropriate for gestational age" (36 weeks). Pet. Ex.

¹⁶ These pamphlets also accompanied petitioner's April 8, 2009 response to respondent's motion to dismiss. They are apparently the documents that petitioner intended to file as Pet. Ex. 6, but which were missing from petitioner's February 12, 2009 evidentiary filings.

¹⁷ Respondent also notes a claim that Tyler contracted measles as a result of his brother's MMR vaccination, which occurred after November 3, 2000, "is not a viable vaccine injury claim under the Vaccine Act, which requires that, except for specific circumstances related to [the] oral polio vaccine, the vaccine recipient also be the injured party." Res. Resp. at 2 (citing § 11(c)(1)). Respondent's position is correct.

¹⁸ The Apgar score is a numerical expression of a newborn's condition. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1682. It is calculated one minute and five minutes after birth by adding the points awarded (2, 1, or 0) to five physiological markers: heart rate, respiratory effort, muscle tone, reflex

2, p. 5. Tyler passed his infant hearing screen on November 14, 1996. *Id.*, p. 4. He was subsequently discharged from the hospital on November 16, 1996. *Id.*, p. 7.

The medical records from Tyler's first five months of life reflect problems with thrush,¹⁹ feeding, vomiting, diarrhea, fever, and congestion. See Pet. Ex. 4, pp. 1-6. The first notation of what would become a chronic problem with thrush was made during Tyler's two week well-baby check. *Id.*, p. 1. At this visit, Tyler received his initial hepatitis B vaccine. *Id.* He continued to receive routine childhood immunizations until August 12, 1999. See Pet. Exs. 5, p. 2; 9; 10.

Notes from Tyler's well-child visits reflect very little progression in speech between nine and 18 months of age.²⁰ See Pet. Ex. 4, pp. 9, 11-12. Although it is unclear from the records when his pediatrician or parents first became aware of his speech problems, an entry on September 8, 1999 indicated that Tyler had an appointment for testing for an early intervention program. *Id.*, p.15. Based on the undated telephone call note above this entry, the early intervention testing involved Tyler's speech. *Id.* On November 18, 1999, when Tyler was three years of age, he underwent a speech evaluation, based on a referral from his pediatrician, Dr. Andrea Cramer. Pet. Ex. 26, pp. 71-79. Although Tyler's receptive language skills were deemed "normal," his articulation was determined to be severely impaired. *Id.*, pp. 71, 73.

In a subsequent speech evaluation on December 8, 1999, Tyler's articulation was described as "severe disorder – makes a few phonemes correctly." *Id.*, p. 59. The evaluator recommended speech therapy. *Id.*, p. 62. Tyler's pediatric records also reflect this diagnosis, with a notation of "speech delay" made on the same date as his speech evaluation. Pet. Ex. 4, p. 16.

Tyler was seen at a different pediatric practice in August, 2000. Notes from the initial visit indicate that Tyler's development was normal, except for his speech and vocabulary. Pet. Ex. 8, p. 6. At this visit, parental concerns regarding speech and Tyler's diet were noted. *Id.* Although the records do not indicate why, Tyler was referred to a neurologist on September 1, 2000. *Id.* An undated telephone call note immediately following this entry reflects a call from a Dr. Rios,²¹ with notes indicating "PDD spectrum," a referral to a "preverbal program," indication of a family history of seizure disorders, and Tyler's language disorder, suggestive of Landau-Kleffner

irritability, and color. *Id.*

¹⁹ Thrush or "oral candidiasis" is a fungal infection caused by yeasts. DORLAND'S at 1924. It is characterized by white spots in the mouth and on the tongue. Thrush is a common symptom of immune system disorders, including CMC. *Id.*

²⁰ Tyler had "+2" words at nine months, four words at 12 months, and three to four words at 15 months. Pet. Ex. 4, pp. 9-11. At 18 months he had "+3" words and was noted to be a babbler. *Id.*, p. 12.

²¹ Doctor Rios is identified in another record as a developmental pediatrician. Pet. Ex. 8, p. 8.

syndrome. Pet. Ex. 8, p. 6. Petitioner called the pediatric office on September 1, 2000, to report that Dr. Rios had evaluated Tyler and thought he might have a rare genetic form of autism. Doctor Rios had several suggestions for evaluation and therapy for Tyler. *Id.*, p. 8.

By September, 2000, concerns about Tyler's development had spread beyond speech. A record dated September 8, 2000, reflects that, in addition to having "few words," Tyler was a finicky eater and had tactile defensiveness and light sensitivity. These entries are followed by the notation "PDD," an abbreviation standing for Pervasive Developmental Disorder. Pet. Ex. 4, p. 21.

On September 11, 2000, during a sick-child visit for thrush, the physician noted that Tyler would not eat unless his food was mashed and his mother made him. The physician noted "mom very concerned" followed by "[symptoms] of developmental delay and sensory integration disorder." *Id.*, p. 7. A note from a September 26, 2000 pediatric visit recorded a history of "problems [with] speech . . . x [for] 16 mo." *Id.*, p. 9. This would place onset of Tyler's speech problems in May, 1999.

Tyler continued to have thrush throughout childhood. See Pet. Exs. 4 and 8; see also Pet. Ex. 13, p. 2 ("The mother recalls that Tyler used to have frequent bouts of thrush since 2 weeks of age."). On October 5, 2000, Tyler had his first visit with Dr. Richard Wasserman, an immunologist, to rule out CMC. See Pet. Ex. 15, pp. 2-3. Doctor Wasserman noted "Candidiasis," "R/O [rule out] Deficiency, Cell Mediated Immune (Chronic Mucocutaneous)," and "? of Autism, Infantile." *Id.*, p. 2. During the visit, Tyler underwent a candida skin test,²² which yielded normal results. *Id.*, p. 4.

On October 16, 2000, Dr. Wasserman ordered a series of blood tests, resulting in Tyler's CMC diagnosis. See *id.*, pp. 4, 41, 43, 47. Ms. Speights was informed of the diagnosis on November 22, 2000. *Id.*, p. 43. In a December 7, 2000 letter written to Dr. John Foster, Dr. Wasserman indicated that "[t]his disorder was not induced by immunization. I can make no comment about a possible relationship between immunization and other problems." *Id.*, p. 47.

On February 14, 2001, Tyler was seen by Dr. Gerald So for a neurological evaluation, having been referred because of "aphasia²³ and staring spells." Pet. Ex. 13, pp. 2-3. During the visit, Ms. Speights informed Dr. So that "Tyler was quite vocal until 20 months of age," but that shortly after the "DaPT [sic] shot,"²⁴ he "began to

²² Skin tests are used to determine prior exposure or immunity to an infectious disease and to assess how an individual's immune system will respond to the disease. DORLAND'S at 1899. A common example is the tuberculin skin test. *Id.*

²³ Aphasia generally refers to the inability of self-expression by speech, writing, or signs due to brain injury or disease. DORLAND'S at 115.

²⁴ The vaccination records indicate that Tyler received a DTaP vaccination on June 19, 1998, when he was 19 months of age. Pet. Ex. 5.

regress with his language.” *Id.*, p. 2. She reported that Tyler “stopped talking and began pointing at things,” “began to have repetitive emesis,” and “began to have episodes of staring.” *Id.* Ms. Speights further reported that “[a]t age 3 yo, shortly after his varicella vaccine, [Tyler] began having more episodes of staring.”²⁵ *Id.* Aside from Tyler’s language, the only abnormality Dr. So observed was “toe walking.” *Id.*, p. 3. Doctor So referred Tyler for EEG monitoring to determine whether his staring spells were epileptic in origin. See *id.*; Pet. Ex. 21, p. 1. The results of this study were normal.²⁶ Pet. Ex. 13, p. 4.

Although more recent medical records were filed, they are not relevant to a determination of the timeliness of the petition.

III. Analysis.

A. Legal Standards.

The Vaccine Act provides that, in the case of:

a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

§ 16(a)(2). According to the Federal Circuit, the date on which the statute of limitations begins to run “is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition.” *Cloer*, 654 F.3d at 1339. Additionally, the Federal Circuit made clear that the triggering of the statute of limitations “does not depend on the knowledge of a petitioner as to the cause of an injury.” *Id.* at 1338. In *Cloer*, the Federal Circuit held that “a discovery rule cannot be read into the Vaccine Act statute of limitations.” *Id.* at 1339.

Prior to its decision in *Cloer*, the Federal Circuit, in *Markovich* explained the differences between “symptom” and “manifestation of onset,” as those words are used in the Vaccine Act. *Markovich*, 477 F.3d at 1357. A “symptom” may be associated with more than one condition, and it may be difficult for a lay person to connect a symptom

²⁵ Tyler received a varicella vaccination on August 12, 1999, when he was about two years and nine months old. Pet. Ex. 10.

²⁶ “[Tyler] had several push buttons for episodes of anger outbursts, staring, headaches, episodes of forgetfulness, and perseveration. None of these episodes showed any epileptic correlates.” Pet. Ex. 13, p. 4. During the February 14, 2001 visit with Dr. So, Ms. Speights reported that most of Tyler’s staring spells seemed to occur after anger outbursts. *Id.*, p. 2.

with a particular injury. *Id.* “Manifestation of onset,” on the other hand, is an event more clearly associated with an injury. *Id.* Neither a symptom nor the manifestation of onset requires a doctor’s definitive diagnosis of a condition. *Id.* at 1358 (quoting *Brice*, 36 Fed. Cl. at 477 (1996)). The earlier of the two, however, will trigger the statute of limitations. *Markovich*, 477 F.3d at 1357; see also *Cloer*, 654 F.3d at 1335 (“The analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset.”).²⁷

Although equitable tolling of the statute of limitations is permitted in Vaccine Act cases, petitioners must establish specific circumstances to justify its application. *Cloer*, 654 F.3d at 1344-45. The Federal Circuit has noted that appropriate circumstances include incidents of fraud or duress or where a procedurally defective petition was timely filed. *Id.*

B. Findings of Fact and Conclusions of Law.

Under *Cloer*, a determination of a petition’s timeliness requires the identification of the first symptom or manifestation of onset of the alleged vaccine injury. This determination, however, has been made more difficult in Tyler’s case because of the ambiguity in petitioner’s pleadings addressing the alleged injury. Because the second amended petition refers to developmental regression (without explicit mention of autism or an ASD), as well as CMC, I will assess the timeliness of the petition for the claims of developmental delay or regression and CMC separately.

In light of the November 3, 2003 filing date, the first symptom or manifestation of onset of Tyler’s developmental delay or regression and/or his CMC may not have occurred before November 3, 2000. Likewise, petitioner’s significant aggravation claim is subject to the same three-year time period. That is, the “change for the worse” in Tyler’s developmental delay and/or CMC disorder must have occurred on or after November 3, 2000 for the petition to be considered timely. See § 33(4) (defining “significant aggravation”).

1. The Developmental Delay, Regression Claim, or Autism Claim.

Petitioner claims that the triggering date for application of the statute of limitations is August 8, 2001, when Tyler was diagnosed with “speech loss as being a form of autism.” Pet. Resp. to Mot. to Dismiss at 3.

²⁷ Petitioner’s reliance on *Setnes* was not reasonable as *Setnes* was effectively overruled by *Cloer*, and, in any event, does not constitute binding precedent. *Hanlon v. Sec’y, HHS*, 40 Fed. Cl. 625, 630 (1998) (noting that decisions of special masters and judges of the Court of Federal Claims constitute persuasive, but not binding authority); see also *Guillory v. Sec’y, HHS*, 59 Fed. Cl. 121, 124 (2003) (“The special master and this court are bound . . . by the decisions of the . . . Federal Circuit.”), *aff’d*, 104 Fed.Appx. 712 (Fed. Cir. 2004).

I find that the first symptom of Tyler's speech delay occurred by 18 months of age (around May, 1998), when his speech development appeared to have plateaued. Tyler had approximately the same number of words at this point as he had at 12 months of age. Pet. Ex. 4, pp. 9-12. There is no indication in the medical records that Tyler's pediatrician or his parents were concerned at this point in time. However, according to Ms. Speights's own statement, she was concerned shortly after this point. In her words, "Tyler was quite vocal until about 20 months of age" (Pet. Ex. 13, p. 2), placing onset of speech regression at around July, 1998. Although this statement was recorded in a medical history provided in February, 2001, Ms. Speights dated the regression in Tyler's speech to his DTaP vaccination (referred to by her as his "DaPT" vaccination). *Id.* The vaccination records reflect administration of Tyler's only DTaP vaccination on June 19, 1998, when he was 19 months old. Tyler's speech delay was formally diagnosed in November and December 1999. Pet. Exs. 4, p. 16; 26, pp. 59, 71. In September, 2000, Ms. Speights reported to Tyler's pediatrician that he had been having problems with speech for the previous 16 months, placing onset around May, 1999. Pet. Ex. 8, p. 9.

Regardless of the date used, both Ms. Speight's dating and the pediatric records reflect the first symptoms of speech delay in the spring or summer of 1998. Even using the initial diagnosis date (December, 1999), Tyler's speech delay had manifested nearly year too soon for a claim based on speech delay to be timely.

Tyler's speech delay later led, in part, to his autism diagnosis.²⁸ The medical records also reflect behavioral symptoms consistent with autism (finicky eating and sensory integration concerns) in September, 2000. Pet. Ex. 8, p. 7. Moreover, three medical records from September, 2000, including a report by petitioner herself, reflect concerns about autism or PDD. *Id.*, pp. 7-9. These references were made about 10 months too soon for this claim to be considered timely.

I thus hold that a vaccine injury claim for developmental delay, regression, or, to the extent Tyler's autism remains a claimed injury, autism spectrum disorder, is time-barred.

2. The CMC Claim.

Petitioner claims that the triggering date for application of the statute of limitations is November 3, 2000, the date Tyler was diagnosed with CMC. Pet. Br. at 7. According to petitioner, November 3, 2000, is the date by which she "knew or should have known that the vaccines injured Tyler," and thus that her petition was timely filed on November 3, 2003. *Id.* Unfortunately, it is not the diagnosis date that triggers the running of the statute of limitations; it is the date of the first symptom or manifestation of onset.

²⁸ Speech delay is often the first symptom of autism noticed by caregivers, usually between 18-24 months of age. See *White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064, at *5, *7-8 (Fed. Cl. Spec. Mstr. Nov. 22, 2011); see also *Carson v. Sec'y, HHS*, 727 F.3d 1365, 1370 (Fed. Cir. 2013) ("[I]t was not arbitrary and capricious for the Chief Special Master to find that severe speech delay . . . was the first objectively recognizable symptom of autism.").

I find that the first symptom of Tyler's CMC was the thrush he exhibited on January 21, 1997, at his well-baby checkup. Pet. Ex. 4, p. 1; see *also* Pet. Ex. 13, p. 2 ("The mother recalls that Tyler used to have frequent bouts of thrush since 2 weeks of age."). Thrush is commonly recognized as a symptom of immune system disorders, including CMC. See DORLAND'S at 1924; see *also supra* note 19. I thus hold that petitioner's claim that Tyler's vaccines caused his CMC is time-barred, as the first symptom of his CMC occurred more than three years before November 3, 2000.

3. The Significant Aggravation Claim.

Petitioner claims that Tyler suffered an injury, or in the alternative, suffered an aggravation of a medical condition due to the multiple vaccines he received. Second Am. Pet. at 5. Specifically, petitioner asserts that, following Tyler's CMC diagnosis, his physicians determined that his CMC was being aggravated by his vaccinations. Pet. Br. at 6; Second Am. Pet. at 3 (citing Pet. Ex. 8, p. 11).²⁹

Tyler received his last vaccine on August 12, 1999, according to the medical records filed. Pet. Ex. 10. His medical records do not show a worsening of his CMC following his final vaccination, nor did petitioner reference any medical records to support her claim. Tyler's condition, as is paradigmatic of chronic diseases, was persistent. On September 26, 2000, Tyler's doctor noted his "problem [with] yeast" (Pet. Ex. 8, p. 9), a problem that, according to Ms. Speights's own report, had frequently manifested since Tyler was two weeks of age (Pet. Ex. 13, p. 2). Thus, any claim that a vaccination aggravated Tyler's CMC is time-barred.

Although petitioner did not specifically allege that Tyler's vaccinations significantly aggravated his developmental delay, any such claim also would be time-barred. Tyler's medical records do not show a worsening of his developmental delay following his final vaccination on August 12, 1999. On December 8, 1999, nearly four months after Tyler's final vaccination, and nearly a year before the earliest date by which a significant aggravation claim could be considered timely, speech delay was noted in his pediatric records (Pet. Ex. 4, p. 16), but, as noted above, speech delays were present prior to this vaccination (see, e.g., Pet. Ex. 8, p. 9 (Ms. Speights's own report on September 26, 2000, that speech problems had been present for 16 months)). Thus, any claim that a vaccination aggravated Tyler's developmental delay is time-barred.

²⁹ On December 6, 2001, Tyler's doctor noted, "[b]ecause of neurological workup and dx [diagnosis] of [CMC] hold shots for now." Pet. Ex. 8, p. 11. Petitioner relies on this notation to support her significant aggravation claim. Such statements, however, do not necessarily "support an inference that the treaters believed there was a logical link between vaccination and injury." *Rickard v. Sec'y, HHS*, No. 09-729V, 2011 WL 1979601, at *12 (Fed. Cl. Spec. Mstr. Apr. 11, 2011). I note that the physician who diagnosed Tyler's CMC categorically stated that Tyler's CMC "was not induced by immunization." Pet. Ex. 15, p. 47

4. Equitable Tolling.

In her response to my April 12, 2013 order to show cause, petitioner argues that she “was not aware that the [Vaccine Program] existed at the time Tyler received his vaccines.” Pet. Show Cause Resp. at 2. She adds that Tyler’s physicians never provided her with information about the Program as they were legally obligated to do, and that the documents she was given at the time of Tyler’s vaccinations did not mention the Vaccine Program. *Id.* at 2-3. Petitioner asserts that had she been adequately informed, she would have filed her petition sooner.³⁰ *Id.*

As discussed below, petitioner’s equitable tolling argument lacks factual support. Moreover, even assuming that petitioner’s assertions are factually correct, to apply equitable tolling under these circumstances would contravene the intent of Congress, as evidenced by the legislative history of the Vaccine Act. Petitioner has failed to point to any other circumstances that justify equitable tolling.

a. A Lack of Factual Support for Equitable Tolling.

Petitioner’s Exhibit 39 contains copies of Vaccine Information Statements [“VIS”] for the polio (two pages), DTP (two pages), hepatitis B (four pages), and Hib (one page) vaccines. Pet. Ex. 39, pp. 1-9. The Hib VIS is dated 1990, and the other three VIS are dated 1992.³¹ *Id.* Petitioner states that she received these VIS at the time Tyler received his vaccinations.³² Pet. Show Cause Resp. at 3. Petitioner adds, however,

³⁰ Petitioner raised these arguments as the basis for retracting her February 15, 2013 motion for a decision dismissing her petition. On May 13, 2013, petitioner filed copies of vaccine information pamphlets which she claims she received at the time of Tyler’s vaccinations. Pet. Ex. 39; Pet. Show Cause Resp. at 3. Petitioner wishes for the court to consider the arguments in favor of equitable tolling she raised on May 13, 2013.

³¹ More current versions of the VIS may have been available between 1996 and 1998, when Tyler received those vaccines. The Centers for Disease Control [“CDC”] states on its website that “VIS are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP [Advisory Committee on Immunization Practices] recommendations that affect the vaccine’s adverse event profile, indications, or contradictions.” CDC, *VIS Frequently Asked Questions*, <http://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html> (last visited Oct. 17, 2013) [hereinafter “VIS FAQ”].

³² The medical records confirm that petitioner received vaccine information materials at the time of Tyler’s vaccinations. The record of Tyler’s vaccinations contains the following statement:

I have been provided a copy of the appropriate Centers for Disease Control and Prevention Vaccine Information Material(s) and have read, or have had explained to me, information about the diseases and the vaccines listed below. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of the vaccines cited, and ask that the vaccine(s) listed below be given to me or to the person named above (for whom I am authorized to make this request).

Below this statement is a multicolumn table, containing vaccination details, such as the type of vaccine and date of administration. Two columns are titled “Vaccine Information Materials Publ. Date” and “Parent/Guardian Initials.” For each of the 13 vaccinations listed on the form, a checkmark was made in

that the materials she received did not contain information about the Vaccine Program. *Id.* at 2-3.

Enacted in 1986, the Vaccine Act mandates that the Secretary of Health and Human Services “develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child . . . receiving a [Table vaccine],” and that “[s]uch materials shall be published in the Federal Register” following “notice to the public and 60 days of comment.” § 26(a)-(b). Currently, and prior to the earliest publication date of the VIS petitioner filed, the materials disseminated by the Secretary must contain “a statement of the availability of the National Vaccine Injury Compensation Program” (§ 26(c)), which took effect on October 1, 1988 (§ 1 (“Effective Date”)).

A review of the Federal Register suggests that at least two of the four VIS petitioner received at the time of Tyler’s vaccinations contained information about the Vaccine Program.³³ On October 15, 1991, a “final rule” concerning the information a health care provider who administers a polio and/or DTP vaccine must provide to a vaccinee or his parent was published in the Federal Register. Included in the required information was the following language: “Get Information About Possible Help: A U.S. government program provides compensation for some persons injured by vaccines. For more information, call this toll-free number . . . OR contact: The U.S. Claims Court.”³⁴ Vaccine Information Materials, 56 Fed. Reg. 51798-01 (Oct. 15, 1991).

The polio and DTP VIS petitioner filed appear to be incomplete. As published in the Federal Register, the final drafts of the polio and DTP VIS, each contain 12 sections. The final three sections are titled: “Get Information About Possible Help,” “What Vaccines Does Your State Require?,” and “Vaccine Administration Record.”

the vaccine materials column and a checkmark and/or the initials “KS” or “GS” were written in the parent/guardian column. Pet. Ex. 5, p. 2.

³³ The hepatitis B and Hib vaccines were not added to the Vaccine Injury Table until August 6, 1997. National Vaccine Injury Compensation Program (VICP): Effective Date Provisions of Coverage of Certain Vaccines to the Vaccine Injury Table, 63 Fed. Reg. 25777-01 (May 11, 1998). Notice of proposed vaccine information materials for those vaccines, including proposed language identifying the Vaccine Program, was published on September 3, 1998. Proposed Vaccine Information Materials for Hepatitis B, Haemophilus influenzae type b (Hib), Varicella (Chickpox), and Measles, Mumps, Rubella (MMR) Vaccines, 63 Fed. Reg. 47026-01. Tyler received his final hepatitis B and Hib vaccines in 1997. Pet. Ex. 5, p. 2. Thus, the hepatitis B and Hib VIS petitioner received at the time of Tyler’s vaccinations may not have contained information about the Program.

³⁴ According to the CDC, “[t]he date for a new VIS’s required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately.” The CDC recognizes, however, that “[a] provider might be reluctant to discard existing stocks of a VIS when a new edition is published.” *VIS FAQ*. I point out that the polio and DTP VIS petitioner filed were published after the final draft containing information about the Vaccine Program was published in the Federal Register. Additionally, even if the health care provider who administered Tyler’s polio and DTP vaccinations failed to discard expeditiously stocks of VIS that did not reflect the 1991 final rule, it is unlikely that that provider would have been distributing such VIS in 1998, when Tyler received his final polio and DTP vaccines.

Vaccine Information Materials, 56 Fed. Reg. 51798-01 (emphasis added). The photocopies of the polio and DTP VIS petitioner filed contain sections 1-3 and 5-9.³⁵ The photocopies, however, do not contain sections 10-12. Based on the layout of the VIS filed, the last three sections of the final drafts would have been printed on a third page of the 1992 polio and DTP statements. *Compare* Vaccine Information Materials, 56 Fed. Reg. 51798-01, *with* Pet. Ex. 39, pp. 1-4.

In light of the Secretary's 1991 final rule regarding polio and DTP VIS, the 1992 polio and DTP VIS petitioner filed, and the dates on which Tyler received those vaccines, it is likely that petitioner received information that referenced the Vaccine Program at the time of Tyler's vaccinations. Petitioner's argument that she had not been adequately informed of the Program and thus that equitable tolling is warranted lacks factual support.

b. Legislative Intent of the Vaccine Act.

Assuming *arguendo* that the VIS petitioner received from Tyler's physicians did not provide information about the Vaccine Program, equitable tolling is nevertheless not warranted. The Vaccine Act's legislative history indicates that equitable tolling should not be applied, even if a petitioner did not receive the Program information required by § 26(d).

The first version of the Vaccine Act, introduced in the Senate, provided an exception to the statutory limitations period for a petitioner who "demonstrates that he or she was not informed [of the Program] as required by [the Vaccine Act]." S. 2117, 98th Cong. § 2115(b) (1983). This exception, however, was omitted from the final bill. S. 1744, 99th Cong. § 2116 (1986) (enacted). Congress clearly considered, and rejected, this proposed exception.

Congress's decision to omit from the Vaccine Act an exception to the statute of limitations for petitioners who were not informed of the Program evinces its intent to hold the uninformed to the 36-month limitations period.³⁶ This is consistent with the use of objective events, rather than subjective knowledge, found in § 16, to start the 36-month clock running. Thus, equitably tolling the statute of limitations for a petitioner whose physician did not inform her of the Vaccine Program would contravene Congressional intent.

³⁵ The final drafts of the polio and DTP VIS in the Federal Register contain identical sections (section 4) concerning "When Should Your Child Get the Polio/DTP Vaccine and Other Vaccines," which includes a table of the "Recommended Schedule of Vaccinations for All Children." Vaccine Information Materials, 56 Fed. Reg. 51798-01. This section does not appear on the copies of the VIS petitioner filed. Due to the table, this section may have been moved to the end of the VIS for formatting purposes.

³⁶ This reasoning is analogous to that used by the Federal Circuit in *Cloer*, where the Court, based on Congress's abandonment of a discovery rule that had been included in prior versions of the bill, concluded that the legislative history clearly established Congressional intent to reject a discovery rule. *Cloer*, 654 F.3d at 1327.

IV. Conclusion.

For the reasons set forth above, petitioner's causation-in-fact and significant aggravation claims were not filed within the Vaccine Act's 36-month statute of limitations. Additionally, there is no basis for applying equitable tolling to this case. Therefore, this case is dismissed as untimely filed. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Chief Special Master